



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **L. Gordon LETTS et al**

Application No: **10/718,060**

Group Art Unit: **1614**

Filed: **June 10, 2003**

Examiner: **Not yet assigned**

For: **Nitrosated and/or Nitrosylated Cyclooxygenase-2 Selective Inhibitors,  
Compositions and Methods of Uses**

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C. F. R. §§1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form.

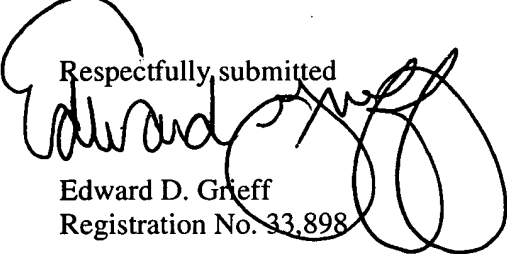
The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents are material to patentability or that the listed documents are prior art.

A copy of the documents listed on the attached PTO-1449 form is submitted herewith. The references listed on Sheet No. 9 of Form PTO-1449 were cited in the prosecution of the corresponding PCT patent application. A copy of each of the references and the search report for the PCT patent application are enclosed.

This Information Disclosure Statement is being submitted before a first office action. No fee is believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219 to maintain the pendency of the present application.

Applicants respectfully request that the Examiner initial and return a copy of the enclosed PTO-1449 form with the next communication from the Patent Office.

Respectfully submitted

  
Edward D. Grief  
Registration No. 33,898

Date: March 2, 2004  
HALE and DORR LLP  
1455 Pennsylvania Avenue, NW  
Washington, DC 20004  
Phone: (202) 942-8490  
Fax: (202) 942-8484

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 9

### Complete if Known

Application Number	10/718,060
Filing Date	6/10/03
First Named Inventor	Letts et al
Group Art Unit	not yet assigned
Examiner Name	not yet assigned
Attorney Docket Number	102258.157 US1

### U.S. PATENT DOCUMENTS

Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,621,000		Arena et al	04-15-1997	
		5,700,947		Del Soldato	12-23-1997	
		5,703,073		Garvey et al	12-30-1997	
		5,780,495		Del Soldato	07-14-1998	
		5,861,426		Del Soldato et al	01-19-1999	
		6,040,341		Del Soldato et al	03-21-2000	
		6,043,233		Garvey et al	03-28-2000	
		6,048,858		Garvey et al	04-11-2000	
		6,057,347		Garvey et al	05-02-2000	
		6,083,515		Garvey et al	07-04-2000	
		6,143,734		Garvey et al	11-07-2000	
		6,297,260		Bandarage et al	01-02-2001	
		6,593,347		Bandarage et al	07-15-2003	
		6,051,588		Garvey et al	04-18-2000	
		6,369,260 B1		Sanniccolo et al	04-09-2002	
		6,512,137 B1		Del Soldato et al	01-28-2003	
		6,323,234		Garvey et al	11-27-2001	
		6,482,846		Garvey et al	11-19-2002	
		6,410,791 B1		Del Soldato	06-25-2002	
		6,573,252 B1		Del Soldato	06-03-2003	

### FOREIGN PATENT DOCUMENTS

Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		WO	94/04484		Matji et al	03-03-1994		
		WO	94/12463		Arena et al	06-09-1994		
		WO	95/09831		Del Soldato	04-13-1995		
		WO	95/30641		Del Soldato	11-16-1995		
		WO	96/32946		Garvey et al	10-24-1996		
		WO	97/31654		Del Soldato	09-04-1997		
		WO	98/09948		Del Soldato	03-12-1998		
		WO	99/45004		Del Soldato	09-10-2000		
		WO	00/06585		Del Soldato	02-10-2000		
		WO	00/25776		Bandarage et al	05-11-2000		

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

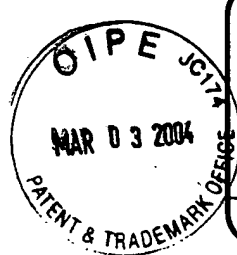
Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

+

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/718,060
				Filing Date	6/10/03
				First Named Inventor	Letts et al
				Group Art Unit	not yet assigned
				Examiner Name	not yet assigned
				Attorney Docket Number	102258.157 US1
Sheet	2	of	9		

[illegible]

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		WO	01/00563		Benedini et al	01-04-2001		
		WO	01/04082		Casraldi et al	01-18-2001		
		WO	01/10814		Benedini et al	02-15-2001		
		WO	01/12584		Del Soldato	02-22-2001		
		WO	02/051385		Trespidi et al	07-04-2002		
		WO	02/053188		Naggi et al	07-11-2002		
		WO	03/084550 A1		Del Soldato	10-16-2003		
		WO	03/013499 A2		Del Soldato	02-20-2003		
		WO	2004/000781 A2		Del Soldato et al	12-31-2003		
		WO	2004/000300 A1		Del Soldato et al	12-31-2003		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.



+

+

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

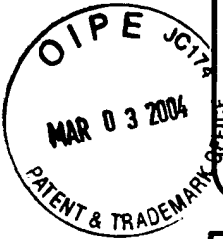
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**Complete if Known**

*(use as many sheets as necessary)*

Sheet	3	of	9
-------	---	----	---

<b>Application Number</b>	10/718,060
<b>Filing Date</b>	6/10/03
<b>First Named Inventor</b>	Letts et al
Group Art Unit	not yet assigned
Examiner Name	not yet assigned
Attorney Docket Number	102258.157 US1

[illegible]

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>				
		WO	00/44705		Del Soldato et al	08-03-2000	
		WO	00/51988		Benedini et al	09-08-2000	
		WO	00/72838		Eek et al	12-07-2000	
		WO	00/61537		Del Soldato	10-19-2000	
		WO	00/61541		Del Soldato	10-19-2000	
		WO	00/61549		Del Soldato	10-19-2000	
		WO	00/61604		Del Soldato	10-19-2000	
		WO	99/44595		Del Soldato	09-10-1999	
		WO	97/16405		Del Soldato	05-09-1997	
		EP	0 904 110		Del Soldato	07-24-2002	

Date	
Considered	

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.



+

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

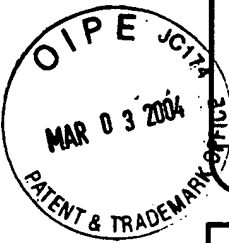
+

**Complete if Known**

*(use as many sheets as necessary)*

Sheet 4 of 9

<b>Application Number</b>	10/718,060
<b>Filing Date</b>	6/10/03
<b>First Named Inventor</b>	Letts et al
<b>Group Art Unit</b>	not yet assigned
<b>Examiner Name</b>	not yet assigned
<b>Attorney Docket Number</b>	102258.157 US1

[illegible]

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T6
		Office <sup>3</sup>	Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		WO	02/092072 A2		Del Soldato	11-21-2002	
		WO	02/100400 A2		Del Soldato	12-19-2002	
		WO	02/11706 A2		Del Soldato et al	02-14-2002	
		WO	02/11707 A2		Del Soldato et al	02-14-2002	
		WO	02/30866		Del Soldato et al	04-18-2002	
		WO	03/000642 A2		Del Soldato et al	01-03-2003	
		WO	03/000643 A2		Orgini et al	01-03-2002	
		WO	00/00200		Hamley et al	01-06-2000	
		WO	01/87343 A2		Scolnick et al	11-22-2001	
		WO	01/93680 A1		Lai et al	12-13-2001	

Date	
Considered	

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.





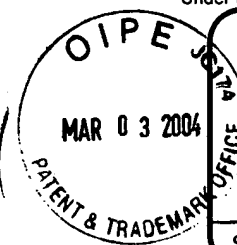
Please type a plus sign (+) inside this box → ☐

PTO/SB/08B (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/718,060
		Filing Date	6/10/03
		First Named Inventor	Letts et al
		Group Art Unit	not yet assigned
		Examiner Name	not yet assigned
		Attorney Docket Number	102258.157 US1
Sheet	6	of	9

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Wallace et al., Trends Pharamcol., Sci., 15(11): 405-406 (1994)	
		Wallace et al., J. Gastroenterol. Hepatol., 9: S40-S44 (1994)	
		Wallace et al., Novel Molecualr Approacehs to Anti-inflammatory Theory, 121-129 (1994)	
		Wallace et al., Gastroenterol., 106(4), Part 2, A208 (1994) Abstract	
		Wallace et al., Eur. J. Pharmacol., 257:249-255 (1994)	
		Wallace et al., Gastroenterol., 107:173-179 (1994)	
		Reuter et al., Life Sciences, 55(1):1-8 (1994)	
		Reuter et al., Gastroenterol., 106 (4), A759 (1994)	
		Cuzzolin et al, Pharmacol. Res. 29(1): 89-97 (1994)	
		Rachmilewitz et al., Gut, 35:1394-1397 (1994)	
		Conforti et al., Agents Action, 40(3): 176-180 (1993)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☐

PTO/SB/08B (08-00)  
Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 7 of 9

### Complete if Known

Application Number	10/718,060
Filing Date	6/10/03
First Named Inventor	Letts et al
Group Art Unit	not yet assigned
Examiner Name	not yet assigned
Attorney Docket Number	102258.157 US1

### OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Carty et al., Agents Actions., 39: 157-165 (1993)	
		Cuzzolin et al, Pharmacol. Res. 31: 61-65 (1995)	
		Barrachina et al., Eur. J. Pharmacol., 281: R3-R4 (1995)	
		MacNaughton et al., Life Sciences, 45: 1869-1876 (1989)	
		Kitigawa et al., J. Pharamcol. Exp. Therp., 253: 1133-1137 (1990)	
		Langford et al., Arterioscler. Thromb. Vasc. Biol. 16: 51-57 (1996)	
		Palmer et al., Nature, 333:664-444 (1998)	
		Wallace et al., J. Clin. Invest., 96: 2711-2718 (1995)	
		Konturek et al., Eur. J. Pharmacol., 239:215-217 (1993)	
		Wallace et al., Expert Opinion Inverstigational Drugs, 4(7):613-619 (1995)	
		Boughton-Smith et al., Eur. J. Pharmacol., 191:485-488 (1990)	

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box → ☐

PTO/SB/08B (08-00)  
Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 8 of 9

### Complete if Known

Application Number	10/718,060
Filing Date	6/10/03
First Named Inventor	Letts et al
Group Art Unit	not yet assigned
Examiner Name	not yet assigned
Attorney Docket Number	102258.157 US1

### OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Elliott et al., Gastroenterol., 109: 524-530 (1995)	
		Wallace et al., Eur. J. Pharmacol., 63-68 (1995)	
		Brown et al., Eur. J. Pharmacol., 103-104 (1992)	
		Williams et al., Cancer Research, 61: 3285-3289 (April 15, 2001)	
		Del Soldato et al., Br. J. Pharmacol., 67:33-37 (1979)	

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.